

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION 4 ATLANTA FEDERAL CENTER 61 FORSYTH STREET ATLANTA, GEORGIA 30303-8960

DEC 08 2016

UNITED PARCEL SERVICE

Mr. Andrew McCarthy Attorney at Law Seal Shield, LLC 2000 North Alafaya Trail, Suite 350 Orlando, Florida 32826

Re: Opportunity to Show Cause

Violation of the Federal Insecticide, Fungicide and Rodenticide Act

Dear Mr. McCarthy:

The U. S. Environmental Protection Agency has reason to believe that Seal Shield, LLC, (Seal Shield) has allegedly violated provisions of the Federal Insecticide, Fungicide and Rodenticide Act, as amended (FIFRA), 7 U.S.C. § 136 et seq. Seal Shield violated Section 12(a)(1)(A), 7 U.S.C. § 136j(a)(1)(A) of FIFRA by distributing and/or selling unregistered pesticides. Further, Seal Shield is also allegedly in violation of Section 12(a)(1)(F), 7 U.S.C. § 136j(a)(1)(F) of FIFRA and the labeling requirements set forth at 40 C.F.R. Part 156, by distributing and/or selling misbranded pesticidal devices. The alleged violations are discussed below in more detail:

A. <u>Sale and/or Distribution of Unregistered Pesticides</u>

On or about January 5, 2015, an authorized representative of the EPA conducted an inspection at the Seal Shield facility located in Orlando, Florida, to determine compliance with FIFRA. The EPA obtained information during the inspection documenting that between February 2014 and February 2015, Seal Shield sold and/or distributed the following unregistered pesticide products on at least 1,026 separate occasions:

- Seal Shield Slim Seal 5-in-One Universal Remote
- Seal Shield Silicone Bumper Case plus Seal Shields Premier for the iPad Mini
- Seal Shield Sea Hawk Waterproof Case for iPad
- Seal Shield Sea Hawk Waterproof Case for the iPhone 5
- Seal Shield Mouse Pad
- Seal Shield Silver Storm Washable Keyboard
- Seal Shield Silver Storm Scroll Wheel Mouse

As set forth in Section 2(u) of FIFRA, 7 U.S.C. § 136(u), and 40 C.F.R. § 152.3, a "pesticide" is defined as any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest or for use as a plant regulator, defoliant or desiccant.

A pest is defined in Section 2(t) of FIFRA, 7 U.S.C. § 136(t), as any insect, rodent, nematode, fungus, weed, or any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other microorganism (except viruses, bacteria, or other microorganisms on or in living man or other living animals) which the EPA declares to be a pest under Section 25(c)(1) of FIFRA, 7 U.S.C. § 136w(c)(1).

Pursuant to Section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A), it is unlawful for any person in any State to distribute or sell to any person any pesticide that is not registered under Section 3 or whose registration has been canceled or suspended, except to the extent that distribution or sale otherwise has been authorized by the Administrator under this Act. Pursuant to 40 C.F.R. § 152.25(a), there is an exception allowed for an article or substance treated with or containing a pesticide to protect the article or substance itself, if the pesticide is registered for such use. However, any pesticide-treated (including silver-treated) product that qualifies for the treated-article exemption must not make potential public health claims, such as "fights germs, provides antibacterial protection, or controls fungus," as well as unqualified "antimicrobial" claims.

At the time of the above-referenced inspection, Seal Shield represented that its products were exempt from registration because they met the "treated article exemption" qualifications under 40 C.F.R. § 152.25(a), because the products are treated with the EPA registered pesticide Ionpure. However, Seal Shield made certain pesticide claims (public health and unqualified antimicrobial claims) concerning the above-referenced products including, but not limited to, those claims identified in the table below, in addition to several other pesticide claims observed on Seal Shield's website. The EPA recently confirmed that Seal Shield continues to make those pesticide claims about the above-referenced

products.

Seal Shield Products	Pesticide Claims
Seal Shield Slim Seal 5-in-One Universal	Silver Seal provides antimicrobial protection
remote	of remote surfaces
Seal Shield Silicone Bumper Case	Contains Silver Seal for antimicrobial product
	protection. This product is Silver Seal
Seal Shields Premier for the iPad Mini	protected. It contains an antimicrobial
	fungistatic agent which protects the product
Seal Shield Sea Hawk Waterproof Case for	and keeps it cleaner, greener and fresher by
iPad	inhibiting the growth of microbial bacteria,
	mold, mildew and fungi on the product's
	surface. Note: Photo of two petri dishes: a)
	untreated and b) treated with Silver Seal and
	claiming > 90% reduction.
Seal Shield Mouse Pad	Silver Seal Antimicrobial Product Protection;
	only Seal Shield medical grade keyboards,
	mic and have antimicrobial properties built-in
	to protect their surfaces.

Based on the EPA's investigation, including the review of all the claims associated with the above-referenced products and all the information collected during the inspection, it was determined that Seal Shield products do not qualify for the "treated article exemption."

The public health and antimicrobial claims made by Seal Shield about its products are not protected under the "treated article exemption" because those claims are specifically prohibited by 40 C.F.R. § 152.25(a). Since the products do not meet the requirements of the "treated article exemption," the EPA has determined that the Seal Shield products are unregistered pesticides and were sold and/or distributed on at least 1,026 separate occasions, in violation of Section 12(a)(1)(A) of FIFRA.

B. <u>Misbranded Violations</u>

The EPA observed that Seal Shield sells and/or distributes the following pesticidal "devices" online at www.sealshield.com:

- Sky 7Xi UV Disinfection for Tablet Computers and Mobile Phones; and
- ElectroClave UV Disinfection/Device Manager

Pursuant to Section 2(h) of FIFRA, 7 U.S.C. § 136(h) and 40 C.F.R. Subpart Z, a "device" is defined, in part, as any instrument or contrivance intended for trapping, destroying, repelling, or mitigating any pests or other form of plant or animal life. In accordance with 40 C.F.R. § 152.500, a device is subject to the requirements set forth in FIFRA, Section 2(q)(1) and 40 C.F.R. Part 156 (Labeling Requirements for Pesticides and Devices). Pursuant to FIFRA, Section 2(q)(1), a device is misbranded if any word, statement, or other information required by or under the authority of the Act to appear on the label or labeling was not prominently placed thereon. Seal Shield's devices above-referenced are misbranded because the affixed labels fail to bear the EPA Producer Establishment number of the final establishment at which the product was produced, as required by 40 C.F.R. § 156.10(f). Seal Shield allegedly sold and/distributed two misbranded pesticidal devices and is therefore, in violation of Section 12(a)(1)(F) of FIFRA,7 U.S.C. § 136j(a)(1)(F).

Pursuant to Section 14(a) of FIFRA, 7 U.S.C. § 136*l*(a), violations of FIFRA and its regulations are subject to a civil penalty of up to \$18,750 for each violation. This letter serves to notify Seal Shield of the opportunity to meet with the EPA to show cause why the EPA should not take an enforcement action with respect to the violations alleged herein. This opportunity to meet with the EPA may either be done in person at our Atlanta office or by telephone conference on a mutually convenient date.

Please contact Marlene Tucker, Associate Regional Counsel at (404) 562-9536 or at tucker.marlene@epa.gov, within fourteen (14) calendar days of the date of this letter to schedule the meeting. If you do not respond, the EPA will assume that you are not interested in meeting to discuss this matter. In that event, the EPA may initiate an enforcement action.

The EPA developed an information sheet entitled "U.S. EPA Small Business Resources" to help small businesses understand federal and state environmental laws and right under the Small Business Regulatory Enforcement Fairness Act. The information sheet can be found on the internet at: www.epa.gov/complaince/resources/publications/incentives/smallbusiness/smallbusresorces.pdf.

If you do not have internet access and would like to request the document in hard copy, please contact Ms. Tucker at the phone number above.

Sincerely,

Kimberly L. Bingham

Chief

Pesticides Section

cc: George Hayslip, Florida Department of Agriculture and Consumer Services